Rehearing Sought In Mensing

Friday, July 22, 2011

The plaintiffs in PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) (not sure why it's all-caps, but that's the way the Supreme Court has it), have sought reargument. Here's a copy of their petition.

Any Supreme Court rehearing petition is a long shot, but in this case, we'd have to say it's worse than that. Mensing is a clear case of "be careful what you ask for, you just might get it."

That's, of course, because of the grounds asserted for rehearing. Plaintiffs now claim that the Court overlooked another supposedly "alternative" theory of liability, specifically:

> "[T]he Petitioner generic drug companies could have "independently" complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate."

Mensing rehearing petition at 1.

Okay…. There are just two slight problems with this "take off the market" theory.

First, it doesn't exist under state law. A "take off the market" theory is merely a reworded variant of a "duty to recall" claim that has been rejected by the Third Restatement and by state law. The Restatement states flatly that there's no common-law duty beyond non-negligently complying with a government-ordered or privately-undertaken product recall. Restatement (Third) of Torts, Products Liability §11 (1998). There's no common-law duty to initiate a product recall in the first instance. In short, state product liability law is not in the business of banning products (whether or not federally approved) from the market.

As for the case law rejecting this sort of theory, we addressed that in our "Total Recall" post that cites law from twenty-eight states. Since that post, we've added

Lance v. Wyeth, 4 A.3d 160 (Pa. Super 2010), and Bartlett v. Mutual Pharmaceutical Co., 2010 WL 3092649 (D.N.H. Aug. 2, 2010), to the list. Notably, one of the states explicitly rejecting duty to recall is plaintiff Mensing's home state of Minnesota. See Kladivo v. Sportsstuff, Inc., 2008 WL 4933951, at *5 (D. Minn. Sept. 2, 2008); Hammes v. Yamaha Motor Corp. U.S.A., Inc., 2006 WL 1195907, at *11 (D. Minn. May 4, 2006); Berczyk v. Emerson Tool Co., 291 F. Supp.2d 1004, 1006 (D. Minn. 2003); McDaniel v. Bieffe USA, Inc., 35 F. Supp.2d 735, 743 (D. Minn. 1999). The issue never comes up in plaintiff Demahy's home state of Louisiana, because a statute delineates the only acceptable product liability claims – and duty to recall/not to sell at all sure ain't one of them.

So the first problem with the plaintiff's latest theory in Mensing is that it doesn't exist at all under state law. In terms of preemption, that also means that it can't possibly serve as the basis of a "parallel" violation claim (Petition at 3) either, since no "parallel" state law claim actually exists.

The second problem with the Mensing petition is that, since the original Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), case over a decade and a half ago, we can't think of a better candidate for preemption – whether asserted against any drug or device maker, branded, generic, or otherwise – than a claim that state law can effectively order a FDA-approved product (or any federally approved product, for that matter) off the market. Such a claim presents an absolute and total conflict of the "yes/no" variety. That is, where a federal agency such as the FDA reviews a product and tells its manufacturer, "yes, you can market this," it's a pretty raw conflict for state common law to tell the same manufacturer of the same product "you should not have marketed this product in our state."

It's hard to come up with a more direct – and thus more conflict preempted – collision between federal and state law. Forget any need for "independent" FDA pre-approval of this or that warning change. Indeed, forget labeling altogether. A "take off the market" claim presents far deeper concerns. Such a claim strikes at the heart of the federal mission that Congress delegated to the FDA, which is to decide what drugs (and other regulated products) should be available to the public in this country.

In that vein, we note that the Mensing petition (at 2) mentions that the court of appeals in Mensing made a thoughtless comment suggesting that the defendant could simply take its FDA-approved drug off the market in response to state tort suits. We also note that even the four Supreme Court dissenters in Mensing, who rejected any and all preemption, were unwilling to find that a "take off the market" claim survived preemption:

"In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. [citing Mensing] Respondents have not advanced this argument, and I find it unnecessary to consider."

131 S.Ct. 2567, 2587 n.8 (dissenting opinion). We strongly doubt that (having already pointed out plaintiffs' waiver) all four of the dissenters would be willing to allow state-law litigants to argue that federally-approved products should not be sold at all. And we doubt even more that any of the majority that found plaintiffs' other theories preempted would allow that a "take off the market" theory to survive.

We don't expect the Mensing petition to be granted, as the theory plaintiffs now advance is even more extreme than it is tardy. That's why it doesn't exist, and why, if it did, it would be preempted.